

REMARKS

This Paper is submitted in response to the Office Action dated May 3, 2006 having a shortened statutory response period ending on August 3, 2006. This Paper is timely submitted within the statutory response period. The Commissioner is hereby authorized to charge any additional fees to Deposit Account number 02-1818.

Claims 76-78, 80-86, 89-94, and 105-108 are pending in this application. Claims 87-88 and 95-104 have been canceled.

Claim 76 was rejected under 35 U.S.C. §112, 1st paragraph as the term “the plurality of sterilized syringe bodies being unwrapped during the transferring” was alleged to be unsupported by the specification. Claim 76 was rejected under 35 U.S.C. §112, 2nd paragraph as the term “unwrapped” was alleged to be confusing. Claim 76 presently recites that the syringe bodies are not wrapped during sterilization and remain unwrapped during the transferring. Claims 76 is supported at page 10 line 29 through page 11 line 14 of the specification. In view of the foregoing, Applicants respectfully request that the §112 rejections be withdrawn.

Claims 105, 106, and 108 were rejected under 35 U.S.C. §102(b) for allegedly being anticipated by U.S. Patent No. 6,800,245 to Erbe et al. (*Erbe*). Claim 107 was rejected under 35 U.S.C. §103(a) for allegedly being obvious in view of *Erbe*. Claims 76-78 and 82-91 were rejected under 35 U.S.C. §103(a) for allegedly being obvious over U.S. Patent No. 6,145,277 to Lawecki et al. (*Lawecki*) in view of U.S. Patent No. 6,164,044 to Porfano et al. (*Porfano*), and *Erbe*. Claims 80-81 were rejected under 35 U.S.C. §103(a) as being obvious in view of *Lawecki* in view of *Porfano Erbe*, and in further view of U.S. Patent No. 3,780,308 to Nablo (*Nablo*). Claims 92-94 were rejected under 35 U.S.C. §103(a) over *Lawecki* in view of *Porfano* and *Erbe* and in further view of U.S. Patent No. 5,207,983 to Liebert et al. (*Liebert*). Claims 87-88 were objected to for allegedly failing to further limit the subject matter of a previous claim. Applicants respectfully disagree with and traverse these alleged rejections and objections for the reasons set forth below.

Claims 87-88 have been canceled rendering moot the objections thereto.

Regarding independent claim 105 and claims 106-108 depending therefrom, Applicants reiterate the well settled axiom of patent law that every word in a claim **must** be considered in judging patentability of the claim. *In re Ochiai*, 71 F.3d 1565, 1572, 37 USPQ2d 1127, 1133 (Fed. Cir. 1995); *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). Thus, when every word of claim 105 is considered, it is clear that *Erbe* has no disclosure or suggestion

of a sterilization method wherein the syringe bodies are irradiated during the transfer of the syringe bodies into a sterile environment as recited in claim 105. *Erbe* merely discloses that cartridges may be irradiated prior to aseptic filling of paste into the cartridges. *Erbe*, col. 12 lines 19-27. *Erbe* has no disclosure whatsoever that cartridge irradiation occurs while the cartridges are being transferred into an isolator. Indeed, the Examiner actually concedes this point as the Examiner acknowledges that *Erbe*'s cartridges are irradiated "in a step *between* providing the cartridges and transferring them to the sterile environment." Office Action dated May 3, 2006 at ¶ 5 (emphasis added). One of ordinary skill in the art would readily recognize that cartridge irradiation that occurs "between" two production steps does not disclose or remotely suggest that cartridge irradiation occurs during cartridge transfer into a sterile environment. With this attempt to equate the term "between" with the explicit claim term "during," it is apparent that the Examiner is dodging the patent law requirement that every word in a claim **must** be considered—particularly in view of Applicants' repeated citation to this requirement. See Applicants' Response to Office Action dated February 14, 2006 at p. 8. Such disregard for the patent law is improper. Accordingly, when every word of independent claim 105 is properly considered, *Erbe* fails to disclose or suggest a sterilization method wherein syringe bodies are sterilized during transfer.

Regarding independent claim 76 and the claims depending therefrom, no combination of *Lawecki*, *Porfano*, *Erbe*, and *Nablo*, *Liebert* discloses or suggests the subject matter of these claims. *Lawecki* teaches away from transferring unwrapped syringe bodies into a sterile environment as recited in independent claim 76. *Lawecki* discloses triple-bagging (*i.e.*, wrapping or triple-wrapping) syringe barrels after barrel formation in order to transport the syringe barrels to a different work area. *Lawecki*, col. 6 lines 24-26; col. 7 line 32 through col. 8 line 15. *Lawecki*'s triple-bagged syringe barrels clearly teach away from the transfer of unwrapped syringe bodies into a sterile environment as recited in claim 76. Teaching away is a *per se* demonstration of non-obviousness. *In re Dow Chemical Co.*, 837 F.2d 469 (Fed. Cir. 1988). Consequently, any combination of *Erbe*, *Porfano*, *Nablo*, and/or *Liebert* with *Lawecki* is likewise *per se* non-obvious.

Even if *Erbe*, *Porfano*, *Nablo*, and/or *Liebert* were combinable with *Lawecki* (which they are not) these references would fail to teach or suggest the subject matter of independent claim 76 and the claims depending therefrom. *Erbe* has no disclosure directed to 1) the formation of cyclic olefin copolymer containing syringe bodies or 2) the transfer unwrapped syringe bodies

into a sterile environment. *Erbe*, has no disclosure whatsoever regarding the composition of the cartridges. Moreover, *Erbe* has no disclosure directed to how the cartridges are placed into the sterile environment. *Erbe* merely discloses that cartridges are sterilized prior to being filled with paste. *Erbe*, col. 12 lines 19-27.

Porfano teaches away from a method of producing sterile prefilled syringe bodies that includes transferring a plurality of unwrapped sterilized syringe bodies into a sterile environment as recited in independent claim 76. *Porfano* discloses syringe barrels placed in a tub in a sealed plastic bag. *Porfano*, col. 7 lines 22-37. The packaged and wrapped syringe bodies are subsequently shipped to a clean room for filling and assembly. *Porfano*, col. 7 line 38 through col. 8 line 17; FIG. 9 and 11. As *Porfano* discloses syringe bodies that are sealed in a plastic bag and transferred to a clean room, *Porfano* teaches away from transferring unwrapped sterile syringe bodies into a sterile environment as recited in independent claim 76. As previously discussed, teaching away is a *per se* demonstration of non-obviousness. *In re Dow Chemical Co.*, 837 F.2d 469 (Fed. Cir. 1988). Consequently, any combination of *Erbe*, *Nablo*, and/or *Liebert* with *Porfano* is likewise *per se* non-obvious.

Nablo fails to teach or suggest a method of producing filled sterile syringes that includes 1) forming cyclic olefin copolymer containing syringe bodies and transferring sterilized syringe bodies into 2) a sterile enclosed isolator class 100 environment as recited in independent claim 76. *Nablo* has no disclosure whatsoever directed to the formation of syringe bodies let alone injection molded cyclic olefin copolymer containing syringe bodies. Moreover, *Nablo* does not disclose a sterile enclosed isolator class 100 environment. Rather, *Nablo* discloses the surface sterilization of packaging material with electron beam radiation. *Nablo*, col. 1 lines 3-8. Ozone, inert gas, secondary x-rays, or a surface sterilizer may be used to maintain a sterile condition during filling and sealing of containers. *Nablo*, col. 5 line 58 through col. 6 line 18. *Nablo*, however, has no disclosure whatsoever directed to an enclosed isolator class 100 environment. Indeed, *Nablo* suggests an open system as Figures 4, 5a, and 5b illustrate an open production process. As *Nablo* has no disclosure directed to 1) forming cyclic olefin copolymer containing syringe bodies, 2) an enclosed class 100 environment, and 3) suggests an open system, *Nablo*, alone or in combination, fails to disclose or suggest the subject matter of independent claim 76.

Liebert fails to fulfill the deficiencies of *Erbe*, and/or *Nablo* as *Liebert* has no disclosure directed to 1) the formation of cyclic olefin copolymer containing syringe bodies and 2) the

sterilization of syringe bodies with electron beam radiation. *Liebert* merely discloses terminal sterilization of filled syringes by autoclaving. *Liebert*, col. 2 lines 8-9.

In summation, *Erbe* fails to disclose or suggest the subject matter of claims 105-108. *Lawecki* and *Porfano* teach away from claims 76-78 and 80-94. Consequently, any rejection based on *Lawecki* and/or *Porfano* fails to establish a *prima facie* case of obviousness. *Erbe*, *Nablo*, and *Liebert*, either alone or in combination, fail to disclose or suggest the formation of cyclic olefin copolymer containing syringe bodies as recited in claims 76-78 and 80-94.

For the foregoing reasons, Applicants respectfully submit that the present application is in condition for allowance and earnestly solicit reconsideration of same.

Respectfully submitted

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